UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/932,227	09/17/1997	ERIC T. FOSSEL		5092

7590 12/14/2004

LORUSSO & LOUD
440 COMMERCIAL STREET
BOSTON, MA 02109

EXAMINER	
MULLIS, JEFFREY C	
ART UNIT	PAPER NUMBER
1711	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/932,227	FOSSEL, ERIC T.	
	Examiner	Art Unit	
	Jeffrey C. Mullis	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-35,38-44,47-53,56-59 and 61-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35,38-41,50,61 and 64-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

All remaining rejections and/or objections follow.

Claims 33-35, 38-41,50, 64-73, 75-77 and 79-81 are rejected under 35 U.S.C. ' 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not disclose oleoresin or capsicum or "neutralization of L-arginine's charge in a complex" or L-arginie chloride or L-arginine glutamate or L arginine butyrate as agents for creating a hostile biophysical environment. While possibly the specification as filed may disclose use of some of these materials as active agents or penetrating agents (distinguished at the bottom of page 7 from hostile biophysical environment creating agents) or the result of neutralization of charge to create a hostile biophysical environment they are not in and of themselves disclosed as agents to create a hostile biophysical environment. The specification as filed does not broadly disclose "the method of topically treating a medical condition" or conditions including "superficial wounds", treatment of bed sores or broadly disclose treatment of "sexual dysfunction"; nor does the specification as filed broadly disclose the use of "alkyls of L-arginine" as is recited by at least claim 67 nor does the specification as filed broadly disclose a method of increasing "growth and repair of cells" as in claim 71. These limitations are therefore new matter.

Claims 33-35, 38-41,50, 70-73, 75-77, 79 and 81 are rejected under 35 U.S.C. ' 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what applicant intends by the term "agent" in that applicant's claims recite choices for the agent which in some cases appear to be active agents as is disclosed by the specification and in other cases uses the term "agent" in a totally different context, namely as a material for altering the hostile biophysical environment. Note for instance claim 73 which recites agents which are not active agents such as high pH etc. While the term "agent" as appears in at least independent claim 33 refers to agents for creating a hostile biophysical environment the term "agent" in the dependent claims is not referred to as "said agent" and as the term "agent" as used in applicants specification refers to active agents as well as agents for creating a hostile biophysical environment and since applicants claims recite agents said to be active agents by the specification, applicants usage of the term "agent" in the dependent claims where unqualified as to the type of agent is confusing.

Numerous "agent(s)" in the above claims are not substances

as is implied by the phrase "concentration of an agent" (note independent claim 33) and thus it is unclear what is intended by the term "agent" as well as the term "concentration" in the context of claims 33-35, 38-41,50, 70-73, 75-77, 79 and 81. Note for instance the claims recite "inclusion of a liposome". Yet it is not at all apparent what or how the term "concentration" applies to "inclusion in a liposome". Phrases such as "inclusion in a liposome", "neutralization of L-arginine's charge in a complex", "high ionic strength environment", "high pH or low pH", "highly hydrophobic environments" make no sense since these materials in fact are not substances and therefore cannot be said to have a concentration associated with them.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. ' 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 64 is rejected under 35 U.S.C. ' 102(b) as being anticipated by Saavedra et al. (U.S. 5,632,981).

Saavedra et al. disclose a process for treating impotence in which nitric oxide releasing material is incorporated into a condom (column 10 lines 20-35). The composition may be in the form of liposomes in a gel or patch at column 9 lines 51-65 and applied topically (column 11 lines 16-26) and may be non-aqueous (note the paragraph bridging columns 11 and 12) since the phosphate buffer (a salt containing material) may be added at column 12 lines 48-56, or "saline" may be added at column 11 lines 40-52.

Claims 65 and 66 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saavedra, cited above.

Saavedra does not explicitly recite "selecting a means of

producing a hostile biophysical environment which increases the migration of the nitric oxide precursor means into the skin". However since salt containing materials are used in the treatment process of Saavedra and since salt containing materials are disclosed by applicant to produce such a function, it would reasonably appear that Saavedra's process inherently meets applicant's limitation.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP ' 2112-2112.02.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-35, 38-41, 61 and 64-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,207,713. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of increasing blood flow is encompassed by the method of increasing blood flow of the patent claims.

Applicant's arguments filed 3-29-04 and 9-29-04 have been fully considered but they are not deemed to be persuasive.

Applicant's substitute specification of 3-29-04 has now been entered.

With regard to the former objection to the specification under 35 U.S.C. ' 132, this objection has been withdrawn since the use of endothelial relaxing factor, nitric oxide as recited by applicant's substitute specification is supported by the claims as originally filed.

With regard to applicant's argument from the section entitled "Rejections Under 35 U.S.C. ' 112, First Paragraph", applicant states that he "addresses the rejection of the claims through amendment of the specification". However a rejection based on new matter cannot be overcome by amending the specification. New matter pertains to matter not previously present from the specification, claims, drawings or Abstract and it was never the position of the Examiner that applicant's claims contained new matter merely because material recited in the claims as amended was not present merely in the specification. The Examiner cannot see where the specification as filed including the claims, drawings and Abstract broadly discloses a method of topically treating a medical condition or conditions including superficial wounds or broadly discloses treatment of sexual dysfunction or the use of a nitric oxide precursor means etc. as set out above. Applicant should point out support for such features in the claims, specification and Abstract as filed.

With regard to applicant's arguments under Section "III. Rejections Under 35 U.S.C. ' 112, Second Paragraph", applicant appears to indicate that the issue is "as containing subject matter not described in the specification". However the issue under 35 U.S.C. ' 112, second paragraph is not whether or not subject matter is described in the specification. The issue under 112 second paragraph is indefiniteness. This issue has not been addressed by applicant.

With regard to applicant's arguments under Section IV, applicant argues that "Saavedra does not teach the use of L-arginine or its derivatives that use the body's own mechanisms to create nitric oxide to treat the claimed conditions". However none of the instant claims rejected over Saavedra recites such a limitation. Applicant is correct that the claims rejected are not product-by-process claims. Nonetheless, the function of increasing the migration of the nitric oxide precursor leans into the skin would reasonably appear to be inherent in the reference given that all other features of applicant's claims are present in the reference.

With regard to the obviousness-type double patenting rejection, the limitations referred to by applicant are not present in the claims rejected under the judicially created doctrine of obviousness-type double patenting.

This Office action is not being made FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Mullis whose telephone number is (571) 272-1075. The examiner can normally be reached on Monday-Friday from 9:30 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be reached on (571) 272-1078. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0994.

J. Mullis:cdc
December 10, 2004

JEFFREY C. MULLIS
PRIMARY EXAMINER
GROUP 1200